K073127 1 of 3

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Trade/Proprietary Name: Blood Collection Needle

DEC 2 0 2007

Classification Information:

(1) Classification Name: Needle, Hypodermic, Single Lumen
(2) Regulation Number: 880.5570
(3) Product Code: FMI
(4) Class: II
(5) Review Panel: General Hospital

2. Submitter Information

Manufacturer Name:

ShanDong WeiGao Group Medical Polymer Products Co., LTD
No.312, Shichang Road
Weihai, Shandong, China, 264209

Contact Person of the Submission:

Ms. Diana. Hong
Mr. Eric. Chen
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, China 20030
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Email: Diana.hong@mid-link.net
Eric.chen@mid-link.net

3. Predicate Device

K number: K061483
Trade Name: VACUETTE® VISIO PLUS Blood Collection Needles
Common Name: Blood Collection Needles

Classification Name: Needle, Hypodermic, Single Lumen
Product Code: FMI

4. Device Description

Blood collection needle is a sterile and disposable medical device. It is consist of a puncturing needle which is punctured into vein, a bottle needle which is insert to the blood collection bottle to collect blood, a needle holder which connects the puncturing needle and bottle needle, two needle caps which protect puncturing needle and bottle needle and a latex cover to protect bottle needle.

The performances of the applicant device of blood collection needle comply with ISO 7864:1993 and ISO9626:1991/AMD: 2001.

The applicant device of blood collection needle is available in 20G, 21G and 22G.

5. Substantially Equivalence Determination

Comparison Analysis:
The applicant device has same classification information, same indications and intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Conclusion:
The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

6. Effectiveness and Safety Considerations

Effectiveness:
All the variant models of the applicant device are evaluated regarding the performance.

Safety Considerations:
With accordance with the Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Systemic Toxicity (Acute), Haemo-compatibility.

Conclusion: The all conducted Biological Evaluation Tests are in compliance with the standards of ISO

10993, "Biological Evaluation of Medical Devices". The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

ShanDong WeiGao Group Medical Polymer Products Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No. 19, Lane 999
Zhongshan No. 2 Road
Shanghai
CHINA 200030

Re: K073127
Trade/Device Name: Blood Collection Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 31, 2007
Received: November 6, 2007

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073127 1 2 1

Indications for Use

510(k) Number:_____

Device Name: Blood Collection Needle

Indications for Use:

Blood Collection Needles is designed for use in the daily blood collection routine when delegated by a qualified practitioner.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K073127